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13. SUPPLEMENTARY NOTES

14. ABSTRACT

Traumatic Brain Injury (TBI) has been referred to as the "signature injury" in Operations Iraqi Freedom and Enduring Freedom, and the Automated Neuropsychological Assessment Metrics (ANAM4), a brief computerized battery of neurocognitive tests, was mandated as a pre-deployment tool in 2008 to help evaluate the effects of TBI. Despite preliminary support for ANAM's correlation with traditional neuropsychological tests, little is known about what constitutes "normal" performance on ANAM4 among cultural/ethnic minority populations, despite their disproportionate representation in the military, the risk of TBI and PTSD during deployment, and the fact that demographic/cultural factors are known to influence performance on many neurocognitive tests. Because of the central role of normative data in interpreting neurocognitive test results, it is important to know whether existing norms are applicable to individuals with different sociocultural backgrounds. The goals of this study are to 1) establish preliminary normative data for ANAM4 in samples of healthy African American Indian, and Hispanic American subjects, and 2) compare the ANAM4 test battery with traditional neuropsychological tests that tap similar cognitive abilities.

15. SUBJECT TERMS

ANAM4, Traumatic Brain Injury, African Americans, American Indians, Hispanic, Computerized Neurocognitive Testing, Normative Data,

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Introduction

The Automated Neuropsychological Assessment Metrics (ANAM4), has been used as a predeployment tool to help evaluate the effects of TBI in the military. Despite preliminary support for ANAM's validity, little is known about what constitutes "normal" performance on ANAM4 among cultural/ethnic minority populations, despite their disproportionate representation in the military, the risk of TBI and PTSD during deployment, and the fact that demographic/cultural factors are known to influence performance on many neurocognitive tests. The goals of this study are to 1) establish preliminary normative data for ANAM4 in samples of healthy African American, American Indian, and Hispanic American subjects, and 2) compare the ANAM4 test battery with traditional neuropsychological tests that tap similar cognitive abilities. Milestones for Year 2 included completing recruitment and testing of 102 subjects to meet the study goal of 180, data entry and cleanup, and the beginning of data analysis.

Body

Year 2 funds acquired from the USAMRMC ORP HRPO September 2011. The approved project timeline is presented in TABLE 1.

TABLE 1: STATEMENT OF WORK: Study timeline

Milestone	Base Line Plan Date	Act Comp Date	<u>Remark</u>
Obtain and set up equipment, pilot testing	11-Jan-2011	27-Dec-2011	Reporting Period: 27- Sep-2010 thru 27-Dec- 2010
Staff training and set up database	11-Jan-2011	27-Dec-2011	Reporting Period: 27- Sep-2010 thru 27-Dec- 2010
Recruitment and testing of subjects	26-Oct-2012	27-Aug-2012	Reporting Period: 27- Sep-2010 thru 26-Oct- 2012
Data entry	26-Oct-2012	3-October-2012	Reporting Period: 27- Sep-2010 thru 26-Oct- 2012
Data analysis	26-Oct-2012		In progress

Administrative and Logistical Matters

USAMCMC ORP HRPO

- Quarterly reports submitted in a timely manner for Year 2.
- Minor budget changes for Year 2 submitted to Elena Bane on 11/29/2011. Changes were approved for Year 2 on 12/1/2012.
- In-progress review teleconference completed on 12/21/2011.
- Six month no-cost extension requested 10/2012.

IRB Approvals

• UTSW Medical Center Continuing Review approved 4/5/2012.

Contracts

- Choctaw Nation subcontract developed, generated, and awarded to assist in the recruitment of American Indian subjects for Year 2.
- Co-investigator subcontract developed, generated, and awarded to augment expertise in cross-cultural research methodology, and adaptations in telehealth and military mental health systems. Modification made to project budget to fund co-investigator one month in Year 1 and one month in Year 2.
- Dr. Hynan, biostatistical consultant, IDR form completed and submitted to assist with database development, management, and statistical analysis.

Meetings

- Study personnel met weekly with the PI to review progress over the course of Year 2. Primary focus has been on recruitment strategies and data collection.
- PI updated co-investigators on progress quarterly via email and phone.

Year 2 Milestones

Recruitment and testing of subjects -COMPLETED

Recruitment strategies in Dallas, TX and Talihina, OK for Year 2.

- "Health Topics Survey Registry" at UTSW, which was established as a project to evaluate challenges faced in subject recruiting. Registry personnel attend events in the community to recruit subjects for studies at UTSW.
- "Find a Clinical Trial" at UTSW website. This website was developed to connect researchers and community members interested in participating in research.
- "Campus News" a weekly mass email updating the UTSW community about research opportunities on campus.
- African American and Hispanic American subjects were recruited in the "Neighborsgo" section of "The Dallas Morning News" for three consecutive Fridays from 12/9/2011-12/23/2011.

- UT Arlington
 - -Dr. Jacob Resch, a UT Arlington co-investigator with Dr. Cullum on another project, assisted with recruitment of Hispanic American and African American subjects.
- Local Businesses and Community Colleges
 - -Flyers were placed at local businesses and community colleges.
- Dallas County Health Fairs
 - -Various health fairs were attended in Dallas County: Hispanic HealthFest 11/12/2011, Native American Awareness Expo 12/6/2011, and HealthFest at KwanzaFest 12/10/2011 &12/11/2011.
- Choctaw Nation Health Services Authority Clinics
 - Flyers were placed in clinics around the state of Oklahoma to assist with recruitment.
 - -All CNHSC employees were sent emails providing information about the study.
- Community Health Fairs
 - Carey Fuller attended health fairs throughout Oklahoma dissemination flyers and info.
- Local Businesses and Community Colleges
 - -Flyers were placed at local businesses and community colleges in southern Oklahoma.
- Ads placed in "Bishinik," the Choctaw Nation of Oklahoma newspaper
 - -Monthly advertisements were placed, with national circulation.

Year 2 recruitment numbers.

- 50 recruitment letters were sent by "Health Topics Survey Registry."
- 112 subjects were screened for Year 2; of these, 105 subjects were eligible, 102 subjects tested for Year 2.

TABLE 2: Number of subjects tested by race/ethnic group for Year 2.

Group	Year 2 Goal	Subjects Tested Year 2	Overall Study Goal	Total Number of Subjects Tested
American Indian	30	38	60	62
African American	30	32	60	70
Hispanic	30	32	60	64
Subtotal	90	102	180	196

Data entry-COMPLETED

Data for Year 2 were collected, scored, double checked, and entered into database by two data operators. Year 2 data entry completed 9/12/2012; data cleaning was completed on 10/8/2012.

Data analysis -IN PROGRESS

Data for Year 2 are in the process of being analyzed after going through all quality control procedures.

Key Research Accomplishments

Key research accomplishments for Year 2 include:

- Recruitment goal of 180 subjects met/exceeded
- Data scored, verified, and cleaned
- Data analysis in progress

Reportable Outcomes

Analysis of the complete data set is in progress; no reportable outcomes to date.

Conclusion

N/A

References

N/A

Appendices

N/A